5. 510(k) SUMMARY

K070584

APR - 2 2008

Submitter's Name:	Duoject Medical Systems Inc.
Address:	50 chemin de Gaspe, Complex B-5 Bromont, Quebec Canada J2L 2N8
Telephone:	(450) 534-3666 ext.24
Fax:	(450) 534-3700
Contact Person:	**Maud Richard**
Date of Summary:	April 1, 2008
Trade Name:	Smart-Rod™ Reconstitution System
Common Name:	Reconstitution system
Classification Name:	Fluid Transfer Set (includes vial adapter) per 21 CFR 880.5440
Predicate Device:	Clip'n'Ject® Reconstitution System (K041691) Bioject® Needle-Free Vial Adapter (K963012 & K043304)

Device Description:

The Smart-Rod™ is a single-use reconstitution device consisting of a pre-assembled vial socket and plunger rod. The Smart-Rod™ is designed to be used together with a pre-filled syringe. The pre-filled syringe would be legally authorized through its own clearance or customer New Drug Application and is not intended to be cleared as part of this premarket notification. The Smart-Rod™ plunger rod replaces the usual plunger rod of the pre-filled syringe and has an integral needle designed to perforate the plunger of the pre-filled syringe for fluid transfer from the syringe to the drug vial (connected using the vial socket) through the internal fluid path in the rod. Once reconstitution is complete, the device permits the transfer of the reconstituted drug product back to the syringe. The integral needle is retracted into the plunger rod by unscrewing the vial socket. The vial socket and vial are discarded, and the filled syringe containing reconstituted drug is ready for use and the drug product may be injected by means of the yet unexposed needle equipping the syringe.

Intended Use:

The Smart-Rod™ is a single use reconstitution device intended for the transfer of a diluent contained in a prefilled syringe to a vial containing a drug product, and the return transfer of the admixture to the syringe.

The Smart-Rod™ is intended for use by physicians, nurses, and other practitioners who routinely administer injections, or patients and other individuals authorized by a physician to administer injections of prescribed medication.

Substantial Equivalence:

The Smart-Rod™ has the same intended use as the predicate devices, with the primary purpose of permitting the transfer of a diluent contained in a syringe to a vial containing a drug product, in order to allow drug reconstitution prior to injection. All devices are single-use and intended to be marketed sterile in individual packaging.

It combines design concepts found in the predicate devices for vial attachment, vial closure piercing and use of the syringe plunger to open a fluid path.

The Smart-Rod™ device is similar in design to Bioject®'s Needle-Free Vial Adapter and West's Clip'n'ject® with respect to the mechanism of attachment to a vial. Its vial closure piercing mechanism is identical to that of Bioject®'s Needle-free Vial Adapter, however unlike the Bioject® Needle-Free vial adapter, the Smart-Rod™ is intended for use with a syringe equipped with a needle, like the West Clip'n'ject® device.

Construction materials include polycarbonate, polyethylene, ABS and steel. Predicate devices use polycarbonate, polyethylene and steel in the operation of the device. ABS is a well established material for other devices of similar intended use.

Performance testing:

16 qualification tests were conducted to demonstrate the operational performance of the device, including attachment to vial and syringe, interaction with the vial stopper and the syringe plunger, operational performance and integrity during use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 2 2008

Ms. Maud Richard
Compliance Engineer
Duoject Medical Systems, Incorporated
50 rue de Gaspe, Complex B-5
Bromont, (Quebec)
CANADA J2L 2N8

Re: K070584
Trade/Device Name: Smart-Rod Reconstitution System
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: March 12, 2008
Received: March 17, 2008

Dear Ms. Richard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

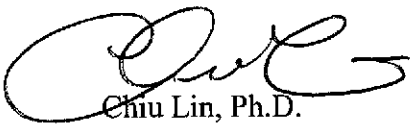
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K070584
Device Name: Smart-Rod™

Indications for Use:

The Smart-Rod™ is a single use reconstitution device intended for the transfer of a diluent contained in a prefilled syringe to a vial containing a drug product, and the return transfer of the admixture to the syringe.

The Smart-Rod™ is intended for use by physicians, nurses, and other practitioners who routinely administer injections, or patients and other individuals authorized by a physician to administer injections of prescribed medication.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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